

Appl. No. : 10/066,302
Filed : January 30, 2002

AMENDMENTS TO THE SPECIFICATION

Please amend the specification as follows:

[0001] This is a continuation-in-part of United States Patent Application Serial No. 09/774,869, filed January 30, 2001, now U.S. Patent No. 6,537,314, which is a continuation-in-part of United States Patent Application Serial No. 09/494,233, filed January 31, 2000, now U.S. Patent No. 6,402,781, and also claims priority under 35 U.S.C. § 119 to United States Provisional Application Serial No. 60/265,995, filed February 1, 2001, the disclosures of which are incorporated in their entireties herein by reference.

[0030] ~~Fig. 2 is a schematic illustration~~ FIGS. 2 and 2A are schematic illustrations of the mitral annuloplasty device shown in FIG. 1.

[0050] Figure 15F shows a cross-sectional view through the line 15F-15F of ~~Figure E~~ Figure 15E of a point of attachment between a deflection element and an elongate body.

[0081] In general, the device 40 defines an overall length from proximal end 42 to distal end 44. Preferably, the axial length is no more than about 10cm, and preferably within the range of from about 2 cm to about 10 cm in an embodiment such as that illustrated in Figure 2 in which the anchor 52 comprises a distal extension of the body 66 for lodging within the great cardiac vein 28. One embodiment of the device 40 includes an elongate flexible body 66 about eight centimeters in length. In such an embodiment, the body 66 is preferably elliptical in cross section so that it will bend in the plane of the coronary sinus 22 and mitral annulus when force is applied to the tensioning element within it, as will be discussed below. Distally the device 40 tapers and transitions to a round cross-section.

[0093] The length of the device 40 from proximal end 42 through the point of attachment 60 is generally no more than about 10 cm, preferably within the range of from about 2 cm to about 10 cm, and, in one embodiment is preferably within the range of from about 6 cm to about 8 cm. The shape of the device 40 is preferably designed to minimize trauma to the vascular intima, both during implantation and following placement. This may be accomplished by rounding all edges which may come into contact with the vessel wall. Thus, the cross-section through the mid-portion 48 of the device, for example, may be elliptical, semicircular or

otherwise rounded, or rectangular with rounded corners. In general, the maximum area of a cross-section of the device 40 will, desirably, be no more than about 15 mm^2 , and preferably no more than about 10 mm^2 , for an embodiment desired for implantation within a human adult. In some embodiments, the maximum cross sectional dimension through the apparatus is no more than about 10 mm.

[0106] The overall length of the embodiment illustrated in Figure 5 is desirably sufficient so that both of the first control line 108 and second control line 110 can extend outside of the patient, while the body 102 extends throughout the pathway of the ventricular girdle 100, substantially as illustrated in Figure 6. For a percutaneous femoral vein access, the overall length of the device is preferably at least about 200 cm, and generally within the range of from about 220 cm to about 260 cm. The length of the body 102 from proximal end 104 to distal end 106 is preferably sufficient to form a closed loop as illustrated in Figure 6. Although both heart size and the shape of the vascular pathway will vary from individual to individual, the length of the body 102 is generally within the range of from about 6 cm to about 12 cm. The body 102 may be injection molded, extruded as a tube, or coextruded over the wire that forms first and second control lines 108 and 110. Preferably, the body 102 either comprises, or is coated with, a material sufficiently compliant to minimize trauma to the vascular intima. In addition, the transverse width of a tissue contacting surface ~~114~~115 on body 102 is preferably sufficient to distribute compressive force to minimize the risks of localized pressure necrosis within the coronary veins.

[0111] According to one aspect of the rotational coupling, the prosthesis 250 is preferably held to resist rotation while rotational coupler 280 is rotated within the prosthesis 250. This may be achieved simply by frictional forces of surrounding tissue as prosthesis 250 is delivered into the desired vessel such as the coronary sinus. According to another example, this may be achieved by providing a releasable interface such as a friction fit 218 between outer member 215 and proximal end portion 252 of prosthesis 250 wherein the frictional engagement of outer member 215 and prosthesis 250 are held in a relatively fixed position while inner member 225 and rotational coupler 280 are rotated. This embodiment is shown in Figure 11A. In addition, or in the alternative to the friction fit interface, a keyed interface may be employed as shown in

Figures 12A-B. According to this mode, a shaped proximal fitting 253 on the proximal end 252 of prosthesis 250 is adapted to mate as a male counterpart into a shaped aperture or fitting on the distal end 212 of outer member 215. This keyed interface allows for rotational coupling between the members in a similar manner as just described for the inner member 225 and rotational coupler 280, and may allow for a more releasable coupling with reduced friction upon axial detachment of the members.

[0136] As previously described herein, the applied force from the forming elements 365, 375, 385 are generally an axial force between the attachment points 361, 371, 381 to the elongate body 320 and a proximal location (not shown) along the elongate body 320 that is proximal to that deflectable portion. According to the specific embodiments shown this force is generally between the attachment points 361, 371, 381 and the proximal end portion of the elongate body 320. The elongate body 320 may generally be held during forced deflection by means of a holding device (not shown) in order to substantially fix the proximal end portion of the elongate body 320 relative to the deflectable portion so that the axial force may be applied between those portions in situ. While the proximal manipulation of the forming elements ~~320-365, 375, 385~~ in order to apply the deflection force to the deflectable portions 360, 370, 380 may be axial as just described, it may in another regard be rotational.

[0139] One particular variation of the patterned voids according to the nested V-pattern embodiment shown in Figures 15A-G is shown in ~~Figure 2H~~ Figure 15H, wherein the nested adjoining portions 340, 350 include interfacing surfaces 342, 352 that have interlocking teeth 344, 354 which are adapted to be locked in a radially deflected pattern in the second configuration. More specifically, the interfacing pattern of teeth 344, 354 are adapted to perform like a ratchet mechanism. By positioning this region along an inner radius of curvature during the bending of forced deflection, compressive forces bring the convexly shaped tooth region 340 deeper into the fitted well formed by the concave receiving region 350. This motion provides an interference between teeth 344, 354 that deflects portion 340 until further motion toward portion 350 clears tooth 354 and recovery locks tooth 344 behind 354. This interactive motion of adjacent portions in voided regions is further represented by bold arrows in ~~Figure 2H~~ Figure 15H

[0146] Additional variations are further contemplated for achieving controlled, desired flexion of the elongate body 320 according to the present embodiments, as is further illustrated by the tapering body design in Figures 18A-B. More specifically, Figure 18A shows a tapering body 320 having a wall 325 with a distally reducing outer diameter between a proximal end portion 321 and a distal end portion 322. As shown, this particular embodiment incorporates the tapered design in combination with the V-shaped grooved void array of Figures 15A-H. However, other void patterns such as a simple transverse groove pattern also previously described may also be suitable with a tapering design, as shown in ~~Figure 15B~~ Figure 18B. The distally tapering wall 325 provides for an increasingly more flexible structure along the distal aspects of body 320. In addition, by maintaining a constant pattern for the grooved voids 330 along the tapering wall, the span of the groove across the circumference of the body 320 increases and percent cross-section of the spine decreases, further contributing to increased distal flexibility. It should be further appreciated that while a continuous taper may be desirable as shown in Figures 18A-B, other tapers including stepped tapers may also be appropriate and are also herein contemplated.